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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/511,405

10/12/2004

Peter Stewart Weisner

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GE HEALTHCARE, INC.
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EXAMINER

MASKELL, MICHAEL P

ART UNIT

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2881

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DELIVERY MODE

08/06/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/511,405	Applicant(s) WEISNER ET AL.	
	Examiner MICHAEL MASKELL	Art Unit 2881	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 8-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 8-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 07/17/2008 has been entered.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-3 and 6-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Strecker, et al (U.S. Patent 3,898,044).

Regarding claim 1, Strecker discloses a device for producing a fluid containing a radioactive constituent, the device comprising a shielded chamber (14) with an opening for receiving an isotope container housing a radioactive isotope; a chamber closure adapted for cooperating with and closing the chamber opening (unlabeled, indicated by reverse cross-hatching relative to side components of chamber 14 in Figs. 1 and 7); a first fluid port comprising a first hollow needle (15 in Fig. 7) projecting into

the shielded chamber from the chamber closure for fluid communication with the isotope container; a second fluid port comprising a second hollow needle (15 in Fig. 1) projecting into the shielded chamber from the closed end of the chamber opposite the chamber closure for fluid communication with the isotope container; first and second compressible buffers mounted so as to surround at least partially the respective first and second hollow needles (column 3, lines 3-5), each buffer providing an outer surface for contact with opposed ends of the isotope container; and a spacer of a predetermined thickness associated with one or each of the first and second compressible buffers for determining the positioning of the isotope container within the shielded chamber (darker cross-hatching in Fig. 7); wherein said isotope container is an ion exchange column (column 2, line 7; also column 4, lines 15-34 describe said isotope container as having the composition of an ion exchange column (i.e. "a column filled with 6 grams of aluminum oxide" wherein "radioactive Tc99m is to separated from Mo99...")) including a frangible seal at each of its opposing ends, said frangible seal adapted to be pierced by and to seal around the respective first and second hollow needles (column 3, lines 3-5).

Regarding claim 2, Strecker discloses a device as claimed in claim 1, wherein with the chamber closure in place in the chamber opening, the first and second hollow needles are fixed in position at each end of the shielded chamber (Fig. 1).

Regarding claim 3, Strecker discloses a device as claimed in claim 1, wherein the spacer is provided with the second compressible buffer at the closed end of the shielded chamber (Fig. 1).

Regarding claim 6, Strecker's invention is a radioisotope generator.

Regarding claim 8, Strecker discloses a device as claimed in claim 1, wherein the isotope container is an ion exchange column (column 2, lines 6-8).

Regarding claim 9, Strecker discloses a device as claimed in claim 1, wherein the first and second hollow needles are each connected via associated fluid conduits (12 and 17a) with a fluid inlet and a fluid outlet respectively.

Regarding claim 10, Strecker discloses a device as claimed in claim 9, wherein the fluid inlet and the fluid outlet each consists of hollow spikes (3 and 18).

Regarding claim 11, Strecker discloses a device as claimed in claim 10 wherein the device further includes an outer housing (33) within which the shielded chamber is located wherein the fluid inlet and the fluid outlet are mounted in the outer housing to provide fluid connections external to the outer housing (opening through which 17a and 12 are fed in housing 33).

Regarding claim 12, Strecker discloses a device as claimed in claim 11, wherein the fluid conduits each consist of flexible tubing which is greater in length than the distance between the hollow needles and their respective fluid inlet or outlet (12 and 17a are greater than the distance between the needles and the inlet and outlet).

Regarding claim 13, Strecker discloses a device as claimed in claim 12, wherein the flexible tubing of each fluid conduit is in length at least twice the distance between the hollow needles and their respective fluid inlet or outlet (in Fig. 1 12 and 17a can be visually seen to be twice as long as the distance between their respective needles and the opening).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-3 and 6-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Strecker in view of Walker, et al (U.S. Patent 5,442,186) and Johnson (U.S. Patent 4,871,087).

Regarding claim 1, Strecker discloses all the limitations of claim 1 (see 102 rejection above); however, assuming *arguendo* that Strecker does not disclose a spacer of predetermined thickness associated with one or each of the first and second compressible buffers for determining the positioning of the isotope container within the shielded chamber, the examiner presents Walker and Johnson as evidence that the addition of said spacers would have been obvious to one of ordinary skill in the art.

5. Walker discloses a container for radioactive source material that includes a spacer (14) that holds the source capsule in place within its shielded jacket, much in the

same way that the isotope container in Strecker is held within the shielded chamber.

One of ordinary skill in the art, being well aware of the undesirability of motion of the isotope container (and the possibility of breakage, etc.) would have had ample motivation to look for means to hold the isotope container in position within the shielded chamber, and would have found in similar fields of radioactive source handling the teachings of Walker providing such a means.

6. Johnson teaches the use of a plurality of spacers for holding a smaller container inside a larger container; which is the same sort of configuration as the isotope container being held inside the shielded chamber (see, for example, claim 7 of Johnson). Although Johnson is not directed towards the handling of radioisotopes, it serves to demonstrate that the use of spacers to position one container within another was notoriously well-known and common-sense to persons of ordinary skill in many, if not most, arts. Further, Johnson's teachings are directed towards the containment and dispensing of ultra high purity chemicals, and, since one working with radioisotopes would preferably be using ultra high purity chemicals, one of ordinary skill in the art would have had ample exposure to such containers during the course of typical lab work.

7. For the above reasons, the use of a spacer of predetermined thickness associated with one or each of the first and second compressible buffers for determining the positioning of the isotope container within the shielded chamber would have been obvious to one of ordinary skill in the art, even if said spacer were determined to not be disclosed by Strecker.

Regarding claims 2, 3, and 6-14, Strecker discloses these limitations as described in the rejections under 35 U.S.C. 102 above.

8. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Strecker (or alternatively over Strecker in view of Walker and Johnson as above) in view of Lu, et al ("Characterization of close-celled cellular aluminum alloys" Journal of Materials Science 36(2001) 2773-2786.).

Strecker discloses the device of claim 1, but fails to teach wherein the material of the first and second compressible buffers is a semi-open cell foam. However, Lu teaches that a semi-open cell foam exhibits highly linear stress versus strain behavior compared with closed cell foam when compressed along the X1 direction (Fig. 7). Thus a properly oriented semi-open cell foam behaves elastically under stress. Since the buffer as claimed is intended to be compressible, elastic material is ideal (see Fig. 8a of Lu, where the elastic behavior allows the material to compress without breaking). It would therefore have been obvious to one of ordinary skill in the art at the time the invention was made to use a semi-open cell foam as the material of the first and second compressible buffers. Doing so would allow the buffers to be compressed without breaking.

9. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Strecker (or alternatively over Strecker in view of Walker and Johnson as above) in view of Homer, et al (U.S. Patent 4,582,638).

Strecker discloses the device of claim 1, but fails to teach wherein the material of the spacer is a closed cell foam. However, Homer teaches the use of closed cell foam

as a gasket in a radioactive material container (column 8, lines 51-60). Homer teaches that such a material is resilient and fluidtight, and prevent damaging loads from being imposed upon a nozzle and tube similar to the needle and tube applied in the present invention. It would therefore have been obvious to one of ordinary skill in the art at the time the invention was made to use closed cell foam as the material of the spacer.

Doing so would provide a fluidtight seal and protect the needle and tube from damaging loads.

10. Claims 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Strecker (or alternatively over Strecker in view of Walker and Johnson as above).

Regarding claim 14, Strecker discloses a method of constructing a radioisotope generator comprising the steps of: providing a shielded chamber (14) with an opening and a chamber closure adapted for cooperating with and closing the chamber opening (unlabeled, indicated by reverse cross-hatching relative to side components of chamber 14 in Figs. 1 and 7); providing a first fluid port comprising a first hollow needle (15 in Fig. 7) projecting into the shielded chamber from the chamber closure; providing a second fluid port comprising a second hollow needle (15 in Fig. 1) projecting into the shielded chamber at the end of the chamber opposite the opening; mounting first and second compressible buffers so as to surround at least partially the respective first and second hollow needles (column 3, lines 3-5), one or each of the compressible buffers including a spacer of predetermined thickness (darker cross-hatching in Fig. 7); introducing an isotope container (13) housing a radioactive isotope through the chamber opening into the shielded chamber so as to contact with the second hollow needle and the second

compressible buffer at the closed end of the chamber wherein said isotope container is an ion exchange column (column 2, line 7; also column 4, lines 15-34 describe said isotope container as having the composition of an ion exchange column (i.e. "a column filled with 6 grams of aluminum oxide" wherein "radioactive Tc99m is to separated from Mo99...")) including a frangible seal at each of its opposing ends, said frangible seal adapted to be pierced by and to seal around the respective first and second hollow needles (column 3, lines 3-5); and closing the shielded chamber by positioning the chamber closure in the opening and bringing the first hollow needle and the first compressible buffer into contact with the isotope container whereby the spacer determines the positioning of the isotope container within the shielded container (Fig. 1).

Although Strecker does not specifically disclose the specific claimed order of performing the above steps, it has been held that the particular ordering of process steps is a *prima facie* obvious difference between an invention's claims and prior art (*Ex parte Rubin*, 128 USPQ 440 (Bd. App. 1959) (Prior art reference disclosing a process of making a laminated sheet wherein a base sheet is first coated with a metallic film and thereafter impregnated with a thermosetting material was held to render *prima facie* obvious claims directed to a process of making a laminated sheet by reversing the order of the prior art process steps.). See also *In re Burhans*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946) (selection of any order of performing process steps is *prima facie* obvious in the absence of new or unexpected results); *In re Gibson*, 39 F.2d 975, 5 USPQ 230 (CCPA 1930) (Selection of any order of mixing ingredients is *prima facie* obvious.)).

In the event that Strecker is found not to disclose the aforementioned spacers,

Strecker in view of Walker and Johnson renders the addition of these spacers obvious for the reasons given in re claim 1 above.

Regarding claim 15, Strecker discloses the method of claim 14, further comprising the step of connecting the first hollow needle to a first fluid conduit and connecting the second hollow needle to a second fluid conduit, but fails to explicitly teach doing this prior to introduction of the isotope container into the shielded chamber. However, since access to the isotope container is very limited once it is introduced into the shielded chamber, common sense would dictate the connection of the needles to the fluid conduits prior to introducing the isotope container into the shielded chamber. It would have been obvious to one of ordinary skill in the art at the time the invention was made to do so, because it would be much easier to access the needles for attachment.

Regarding claim 16, Strecker teaches the method as claimed in claim 15, further comprising the step of locating the shielded container within an outer housing and connecting the first fluid conduit to a fluid inlet in the outer housing and the second fluid conduit to a fluid outlet in the outer housing (see Fig. 1), but fails to teach doing this prior to introduction of the isotope container into the shielded container. However, since the isotope container is radioactive (hence the need for the shielded container), it is much safer to locate the shielded container in the outer housing and connect the fluid conduits before the introduction of the radioactive isotope container. Common sense and ordinary skill in the art would have made it obvious at the time the invention was made to locate the shielded container within an outer housing and connecting the fluid conduits prior to the introduction of the isotope container.

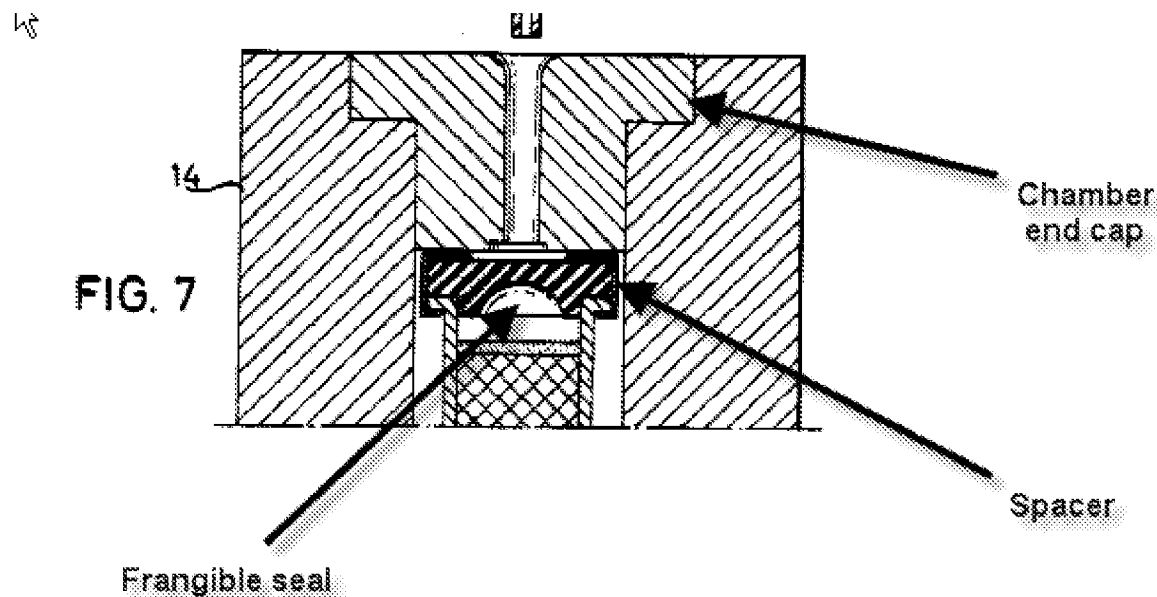
Regarding claim 17, Strecker teaches the method as claimed in claim 16, wherein the first and second fluid conduits are each of flexible tubing which is greater in length than the distance between the first and second hollow needles and their respective fluid inlet and fluid outlet when the chamber closure is in place in the chamber opening and the shielded chamber is positioned within the outer housing (see Fig. 1), but fails to specifically teach whereby all fluid connections can be established prior to installation of the isotope container within the shielded chamber. However, as stated in regards to claim 16, common sense and safety practice would dictate that the introduction of the isotope container within the shielded chamber should only take place after the entire apparatus has been assembled. It would have therefore been obvious to one of ordinary skill in the art at the time the invention was made to establish all fluid connections prior to installation of the isotope container within the shielded chamber. Doing so is the safest way of assembling the apparatus.

Response to Arguments

2. Applicant's arguments filed 07/17/2008 have been fully considered but they are not persuasive.

Regarding claim 1, the applicant's arguments indicate that there appears to still be some confusion as to exactly what component of Strecker's Fig. 7 the examiner is regarding as the spacer. Below is an excerpt from Fig. 7 of Strecker, in which the

examiner has labeled the spacer.



3. As can be seen above, the examiner's interpretation of Fig. 7 includes a spacer that is in contact with both the isotope generator and the end of the shielded chamber, thus functioning as a spacer. In use, Strecker's needle pierces both this spacer and the seal of the isotope generator, causing the spacer to surround the needle. Strecker indicates that "the junctions of nuclide generator 13 are provided with piercable stoppers made of an elastic material." This, in combination with Fig. 7 above, indicates that these stoppers provide both a compressible buffer and spacing.

4. Assuming, *arguendo*, that the above reasoning does not show the disclosure of a spacer by Strecker, alternate grounds of rejection under 35 U.S.C. 103(a) have been provided above, indicating that the use of such a spacer would have been obvious to one of ordinary skill in the art.

5. **Regarding claim 14**, the applicant has advanced analogous arguments to those given for claim 1, to which the same response as above applies. Further, the applicant has argued that Strecker does not disclose the particular claimed order of constructing the apparatus as in the method of claim 14. This argument is persuasive in regards to the anticipation of claim 14, and the corresponding rejection has been withdrawn; however, the claim is newly rejected under 35 U.S.C. 103(a), as the particular ordering of steps in a process is not a nonobvious difference over prior art (see statement of rejection above).

6. **Regarding claim 4**, the applicant has merely stated that “a stopper made of such a semi-open cell foam [as described in Lu] would not provide the necessary degree of sterility and radiological protection required by the present invention.” No evidence has been advanced for this assertion, and the structural benefits cited by the examiner in the rejection as a motivation to use Lu’s semi-open cell foam have not been addressed. The applicant’s argument regarding claim 4 amounts to a mere allegation of patentability without specifically pointing out how the language of the claims patentably distinguishes them from the references; the argument therefore fails to comply with 37 CFR 1.111(b) because it amounts to a general allegation that the claims define a patentable invention.

7. **Regarding claim 5**, the applicant has argued that “a gasket would not be suitable for association with one or each of the piercable stoppers of Strecker to determine the position of the isotope container within the shielded chamber”; however, no evidence or reasoning has been given for this assertion, and the examiner’s

identification of a motivation taught in the prior art for using said gasket has not been addressed. The applicant's argument regarding claim 5 amounts to a mere allegation of patentability without specifically pointing out how the language of the claims patentably distinguishes them from the references; the argument therefore fails to comply with 37 CFR 1.111(b) because it amounts to a general allegation that the claims define a patentable invention.

The applicant has also argued in re claim 5 that "the skilled person would not look to the field of nuclear waste disposal for improvements applicable to a radionuclide generator." In *KSR v. Teleflex* (550 U.S. ____ (2007)), the U.S. Supreme Court found that "When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one." Although Homer's teachings come from a different field of endeavor, the design incentives of providing a resilient, fluidtight seal cited in the rejection could prompt variations in Strecker's apparatus. The adaptation of Homer's teachings to Strecker's would have been well within ordinary skill in the art, and the results predictable, because the configurations of the two apparatus are very similar. Homer teaches a nozzle and tube entering a container in a similar manner to the needle and tube of Strecker's apparatus.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL MASKELL whose telephone number is

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(571)270-3210. The examiner can normally be reached on Monday-Friday 8AM-5PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Kim can be reached on 571/272-2293. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/David A Vanore/
Primary Examiner, Art Unit 2881

/Michael Maskell/
Examiner, Art Unit 2881
31 July 2008